The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

## UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte XU CAO, XINGMING SHI and SHUTING BAI

Appeal No. 2004-2056 Application No. 09/631,411

SEP 2 9 2004

U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

**ON BRIEF** 

Before SCHEINER, ADAMS and GRIMES, <u>Administrative Patent Judges</u>.

SCHEINER, Administrative Patent Judge.

#### **DECISION ON APPEAL**

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 11-14. Claims 1-10 and 15-20 are also pending but have been withdrawn from consideration.

Claim 11 is representative of the subject matter on appeal:

- 11. A method of screening for a compound that disrupts transcriptional repression of a gene, comprising the steps of:
- (a) combining a Smad6/Hoxc-8 protein complex with a gene in the presence and absence of a compound, wherein said gene comprises a Hox DNA binding element; and
- (b) assaying for transcription of said gene, wherein an increase in the level of transcription in the presence of said compound relative to the level of transcription in the absence of said compound is indicative of a compound that disrupts transcriptional repression of said gene.

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No references are relied on by the examiner.

Claims 11-14 stand rejected under 35 U.S.C. § 112, first paragraph (written description), and also under 35 U.S.C. § 112, second paragraph.<sup>1</sup>

We reverse both of these rejections.

#### BACKGROUND

"Smads are mediators of the superfamily of transforming growth factor-β (TGF-β) signaling pathways []. Smad6 and Smad7, antagonize the TGF-β signals []. Smad6 and Smad7, induced by TGF-β or bone morphogenetic protein (BMP), form stable associations with activated type I receptors, which, in turn, block phosphorylation of ligand-induced Smads []. Smad6 also interacts with phosphorylated Smad1 to prevent the formation of an active signaling complex of Smad1 and Smad4 in the cytoplasm []" (Specification, pages 4-5, reference citations omitted). Hox proteins, i.e., "Hox homeobox-containing transcription factor genes . . . play critical roles in the process and patterning of vertebrate embryonic development [] . . . Hox genes are required during vertebrate bud development . . . Hoxc-8 is expressed during human embryo development at high levels in spinal cord, backbone and limbs and at a lower level in heart []" (id., pages 3-4, reference citations omitted).

According to the specification, "Smad6 interacts with Hoxc-8 as a transcriptional corepressor, inhibiting bone morphogenetic protein signaling in the nucleus" (<u>id.</u>, page 5). The present invention is directed to a method of screening for compounds that disrupt transcriptional repression of a gene using the Smad6/Hoxc-8 protein complex.

<sup>&</sup>lt;sup>1</sup> Appellants also ask us to reverse the examiner's objection to the specification's incorporation of certain material by reference (Brief, pages 6-7). However, this is a petitionable, rather than appealable, matter, and we express no opinion as to its propriety. 37 CFR § 1.181.

#### DISCUSSION

### Written Description

According to the examiner, "[t]he specification as filed does not provide any structural information, i.e., sequence, for Smad6 or Hoxc-8 such that the skilled artisan would recognize the common structural features of proteins encompassed in the terms Smad6 and Hoxc-8" (Answer, page 4), thus, the specification does not "reasonably convey . . . that the inventor(s), at the time the application was filed, had possession of the claimed invention" (id., page 3).

We cannot agree with the examiner's conclusion. It appears from the specification (e.g., pages 4-5), and it is not disputed by the examiner, that both Smad6 and Hoxc-8 were known in the art before the present application was filed. Indeed, the examiner acknowledges that "the specification incorporates by reference publications that include sequences for Smad6 and Hoxc-8" (Answer, page 4). It is well settled that "a patent specification need not detail and preferably omits, what is known or understood in the art," <a href="Hybritech Inc. v. Monoclonal Antibodies">Hybritech Inc.</a>, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). This portion of <a href="Hybritech">Hybritech</a> specifically concerns the enablement requirement of 35 U.S.C. § 112, rather than the written description requirement, but we think it appropriate here as well. In our opinion, appellants have "convey[ed] with reasonable clarity to those skilled in the art that, as of the filing date sought, [they were] in possession of the invention," <a href="Yas-Cath Inc. v. Mahurkar">Vas-Cath Inc. v. Mahurkar</a>, 935 F.2d 1555, 1564, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991) (emphasis omitted).

Accordingly, the rejection of claims 11-14 under 35 U.S.C. § 112, first paragraph, is reversed.

#### Indefiniteness

According to the examiner, "the prior art recognized some proteins that would be encompassed by the terms 'Smad6' and 'Hoxc-8', because these names are used in the prior art, however, it is unclear what other proteins would be encompassed in these terms because the names assigned to proteins are not necessarily used consistently in the art" (Answer, page 5).

Nevertheless, the examiner has provided no evidence of inconsistency in the nomenclature of Smad6 or Hoxc-8. Moreover, "the definiteness of the language employed [in a claim] must be analyzed - - not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). Having reviewed the claims in light of the specification, we are in agreement with appellants "that a person having ordinary skill in this art would [] readily recognize the identity of Smad6 and Hoxc-8" (Brief, page 11).

The rejection of claims 11-14 under 35 U.S.C. § 112, second paragraph, is reversed.

## CONCLUSION

We reverse the rejections of claims 11-14 under the first and second paragraphs of 35 U.S.C. § 112, but do not reach the merits of the examiner's objection to the specification's incorporation of certain material by reference.

## **REVERSED**

Toni R. Scheiner

Administrative Patent Judge

Donald E. Adams

Administrative Patent Judge

Eric Grimes

Administrative Patent Judge

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